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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/446,416 | 12/20/1999 | PIETER DE HAAN | 0/97286US | 2292 |

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EXAMINER

DESANTO, MATTHEW F

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|----------|--------------|
| ART UNIT | PAPER NUMBER |
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3763

DATE MAILED: 02/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/446,416

Applicant(s)

HAAN ET AL.

Examiner

Matthew F DeSanto

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "indirectly or directly open connection to the channel and is closed from the outside after preloading;" as well as "the periphery of the plunger defining a chamber," must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The examiner is unclear to what the applicant claimed with the phase "*and is closed from the outside after preloading*, the plunger being capable of closing off and

Art Unit: 3763

opening up the chamber by being displaced.” The examiner read the specification and found on page 5 a door assembly that is capable of closing the preloading section, but the specific structure and function or method of operating is missing or unclear.

The examiner reminds the applicant that no new matter should be entered.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: drawn from the phrase “and is closed from the outside after preloading, the plunger being capable of closing off and opening up the chamber by being displaced,” and the examiner is confused with regards to whether the section between the channel and the chamber is closed or the outside of the barrel (reference #1) and the chamber is closed after preloading.

The examiner reminds the applicant that no new matter should be entered.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 9, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Wiegerinck (USPN 5405324). Wiegerinck discloses an implantation device, comprising of a hollow needle and a body adjoining the needle, the body comprising an elongated part extending along the same axis as the needle, a plunger that can be displaced within the elongated part and the needle, the periphery of the plunger defining a channel in the elongated part and a chamber capable of holding an implant characterized in that the chamber is positioned radially outside the channel and has a directly or indirectly open connection to the channel, the plunger being capable of closing off and opening up the chamber by being displaced, as well as where the implantation device has a chamfered tip and where the plunger has a chamfered tip profile capable of blending with the needle tip profile. Wiegerinck also teaches being able to use a hormonal implant to be injected with the apparatus, and where the implant is held in the chamber. (Fig 1, 2, 3, column 1, 2, and 3).

Art Unit: 3763

7. Claims 1, 3, 5, 7, 8, 9, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaldany (USPN 5562613).

Kaldany discloses a preloadable implantation device comprising a needle, and an elongated part, a plunger, the periphery of the plunger defining a channel, and a chamber. (Figures 3, 6, 7, 8, 9, 10 and entire reference)

Wherein the needle is chamfered. (Figures 9, 10)

Wherein the outside is closed after preloading. (Figures 3,6)

8. Claims 1, 3, 5, 7, 8, 9, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by J. Muir (USPN 1655158).

Muir discloses a preloadable implantation device comprising a needle, and an elongated part, a plunger, the periphery of the plunger defining a channel, and a chamber. (Figures 1-10 and entire reference)

Wherein the needle is chamfered. (Figures 4-9)

Wherein the outside is closed after preloading. (Figures 4-8)

Claim Rejections - 35 USC § 103

9. Claims 1, 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muir as applied to claims 1, 3, 5, 7-10 above, and further in view of Wiegerinck.

Muir discloses the claimed invention but fails to disclose the implant is a hormonal implant.

Wiegerinck discloses the implant as a hormonal implant.

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine Muir with Wiegerinck because it is well known in the medical art to use different types of medication with different types of applications, such as using hormonal pills or tablets, as stated in Wiegerinck. (Column 1, lines 1-25)

Therefore, it would have been obvious to combine the teachings of Muir with Wiegerinck to obtain the invention as specified in claims 1, 3-9.

10. Claims 1, 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaldany as applied to claim 1, 3, 5, 7-10 above, and further in view of Wiegerinck.

Kaldany discloses the claimed invention but fails to disclose the implant is a hormonal implant.

Wiegerinck discloses the implant as a hormonal implant.

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine Kaldany with Wiegerinck because it is well known in the medical art to use different types of medication with different types of applications, such as using hormonal pills or tablets, as stated in Wiegerinck. (Column 1, lines 1-25)

Therefore, it would have been obvious to combine the teachings of Kaldany with Wiegerinck to obtain the invention as specified in claims 1, 3-9.

Response to Arguments

11. Applicant's arguments with respect to claims 1, 3-8 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

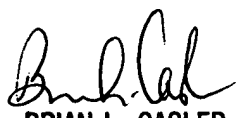
12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 1-703-872-9302 for regular communications and 1-703-872-9303 for After Final communications.

Matthew DeSanto
Patent Examiner, Art Unit 3763
February 3, 2003



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